

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

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| Applicant's or agent's file reference MLC/LCW/2811PC | FOR FURTHER ACTION | See item 4 below |
| International application No. PCT/GB2006/001625 | International filing date (<i>day/month/year</i>) 27 April 2006 (27.04.2006) | Priority date (<i>day/month/year</i>) 27 April 2005 (27.04.2005) |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | |
| Applicant SMITH & NEPHEW, PLC | | |

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| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a). | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | <p>This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p> | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. | <p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | <input checked="" type="checkbox"/> | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. II | Priority | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2). | | | | | | | | | | | | | | | | | | | | | | | | |

| | |
|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Date of issuance of this report 30 October 2007 (30.10.2007) Authorized officer <div style="text-align: center; font-weight: bold;">Dorothee Mülhausen</div> |
| Facsimile No. +41 22 338 82 70 | e-mail: pt01.pct@wipo.int |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2006/001625

International filing date (day/month/year)
27.04.2006

Priority date (day/month/year)
27.04.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61M1/00 A61M27/00

Applicant
SMITH & NEPHEW, PLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2
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Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Lakkis, Angeliki

Telephone No. +31 70 340-4136



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2006/001625

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2006/001625

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 62-72

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 62-72

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2006/001625

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | |
| | No: Claims | 1-61 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-61 |
| Industrial applicability (IA) | Yes: Claims | 1-61 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Re Item III.

Rules 39.1(iv) and 67.1(iv) PCT - Methods for treatment of the human or animal body by therapy and by surgery

Re Item V.

1 Reference is made to the following documents:

D1 : US 2002/161346 A1 (LOCKWOOD JEFFREY S [US] ET AL LOCKWOOD JEFFREY S [US] ET AL) 31 October 2002 (2002-10-31)

D2 : US 2003/050594 A1 (ZAMIEROWSKI DAVID S [US]) 13 March 2003 (2003-03-13)

D3: WO 2005/105176 A (SMITH & NEPHEW [GB]; BLOTT PATRICK LEWIS [GB]; LEE-WEBB JULIAN [GB]; N) 10 November 2005 (2005-11-10)

D4: WO 2005/105175 A (SMITH & NEPHEW [GB]; BLOTT PATRICK LEWIS [GB]; GREEN CLARE [GB]; MARTI) 10 November 2005 (2005-11-10)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 (paragraphs 70-82, figure 16) discloses (the references in parentheses applying to this document):

An apparatus for aspirating, irrigating and/or cleansing a wound, comprising a fluid flow path, comprising a conformable wound dressing (10), having a backing layer (62) which is capable of forming a relatively fluid-tight seal or closure over a wound, at least one pipe (13) which passes through and/or under the wound-facing face to allow irrigation and/or aspiration of the wound, wherein the point at which the at least one pipe passes through and/or under the wound-facing face formings a relatively fluid-tight seal or closure over the wound, when in use; a fluid reservoir (14) connectable by a fluid supply tube to the at least one pipe (13) and at least one

device (14, 12) for moving fluid through the wound dressing to the wound (14) and/or moving fluid from the wound (12), where the apparatus comprises means (12, 14, 13, spacers 46, ridges 50 for distributing suction and irrigation) for applying flow stress to the wound bed.

- 2.2 Note that document D2 (paragraphs 79-83, "flow gradient", figure 16) also discloses all technical features of claim 1, which therefore is not new over D2, either.
- 2.3 Moreover the term "flow stress" is so broad, that any document disclosing the technical features of the preamble of the claim 1 could also be considered as comprising means for applying flow stress to the wound bed, since there is flow and, thus, the wound bed can be considered "stressed" by it.

3 INDEPENDENT CLAIM 60

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 60 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parentheses applying to this document):
A conformable wound dressing (10) comprising a backing layer (62) with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound, at least one pipe (13) which passes through and/or under the wound-facing face to allow irrigation and/or aspiration of the wound, the point at which the at least one pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound in use; where the wound dressing comprises means (13, 46, 50) for ~~means for~~ applying flow stress to the wound bed.
- 3.2 Note that document D2 (paragraphs 79-83, "flow gradient", figure 16) also discloses all technical features of claim 60, which therefore is not new over D2, either.
- 3.3 Moreover the term "flow stress" is so broad, that any document disclosing the technical features of the preamble of the claim 60 could also be considered as

comprising means for applying flow stress to the wound bed, since there is flow and, thus, the wound bed can be considered "stressed" by it.

4 DEPENDENT CLAIMS 2-59, 61

Dependent claims 2-59, 61 do not seem to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

Re Item VI.

Intermediate documents D3 (whole document) and D4 (whole document, especially claim 1) may become pertinent for questions of novelty and validity of priority.